WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 19-145

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

1. Statutory Authority

It appears that s. Phar 7.42 (6) regulates the conduct of nonpharmacists by requiring that prescribers must complete drug utilization review and consulting requirements under certain circumstances within an automated direct-to-patient dispensing system. The board should more specifically describe its authority to regulate prescribers in this manner.

2. Form, Style and Placement in Administrative Code

a. The rule does not contain a "subchapter II". Should subchs. III-VI be renumbered accordingly?

b. In s. Phar 7.02 (1), further subdivisions should be lettered paragraphs.

c. In s. Phar 7.05, 7.07, and 7.62, a period should be inserted at the end of each section title.

d. In s. Phar 7.14 (2) (e), the comma after "Notwithstanding" should be removed and "par" should be replaced by "pars.".

e. The board should revise s. Phar 7.14 (3) (a) and (b) so that each subunit following an introduction forms a complete sentence when read with the introduction. [s. 1.03 (3), Manual.]

f. The material in s. Phar 7.08 (1) (a) to (h) and (2) (a) 1. to 8. appear to be redundant. Consider deleting the material in s. Phar 7.08 (1) as it is unclear for what purpose that material serves.

g. The definitions for "direct supervision" and "general supervision" are both numbered s. Phar 7.60 (2).

h. The board should revise s. Phar 7.62 (3) (a) to (d) so that each subunit following an introduction forms a complete sentence when read with the introduction. [s. 1.03 (3), Manual.]

4. Adequacy of References to Related Statutes, Rules and Forms

a. The plain language analysis section of the rule summary appears to describe the substance of the proposed rule, but does not indicate how the proposed rule differs from the current ch. Phar 7. The reader would benefit from additional explanation of how the proposed rule changes the current rule.

b. The material in s. Phar 7.02 (1) for what must be specified in a prescription drug order generally matches the statutory requirements under s. 450.11 (1), Stats., except that the statute requires the symptom or purpose for which the drug is being prescribed to be specified on the order in certain limited circumstances, but the rule contains no such requirement. Should the rule be changed to match the statute, or should the board delete the material in s. Phar 7.02 (1) and instead include a cross-reference to the statutory list of prescription drug order requirements?

c. The material in s. Phar 7.05 (2) for what must be disclosed on a prescription drug or device label differs in a number of ways from the statutory label requirements under s. 450.11 (4) (a), Stats. For example, the statute requires that "Directions for use of the prescribed drug or device as contained in the prescription order" must be included in the label, but the rule contains no such requirement. Furthermore, the rule appears to require items on the label not required by statute, such as the rule's requirement that "Written or graphic product descriptions" be disclosed on the label. Should the material be changed to more closely match the statute, or should the board delete the material in s. Phar 7.05 (2) and instead include a cross-reference to the statutory list of label requirements?

d. In s. Phar 7.05 (4), "Subsection" should replace "Sub.".

e. For clarity, should the material in s. Phar 7.12 include a reference to s. 450.033, Stats.?

f. The material in s. Phar 7.14 (2) (e) references "the pilot program validation process" but does not adequately identify the pilot program, including what entity administered the pilot program.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In s. Phar 7.01 (4), the board should choose a single term, either "verbal" or "oral" and use it consistently throughout the subsection.

b. The material in s. Phar 7.07 (1) should be revised for clarity. Though the plain language analysis section of the rule summary and references to s. Phar 7.07 (1) within the proposed rule suggest a final check is required, the rule could be modified to make clear that a final check is required and that the final check must include a review of the items specified in s. Phar 7.07 (1) (a) to (c). Furthermore, the material in s. Phar 7.07 (1) also needs revision so that each subunit following an introduction forms a complete sentence when read with the introduction. [s. 1.03 (3), Manual.]

c. Section Phar 7.50 (3) provides that the definition of "institutional pharmacy" "is not for the purposes under s. 450.09 (1) (a), Stats.". Though the rule does not alter the definition of "institutional pharmacy" that applies to ch. Phar 7 under s. Phar 1.02 (4), consider clarifying whether the s. Phar 1.02 (4) definition satisfies the requirements of s. 450.09 (1) (a), Stats. Additionally, the s. Phar 7.50 (3) definition only applies within subch. V of ch. Phar 7, though the term "institutional pharmacy" is used elsewhere in the rule. Is it the board's intent to apply to s. Phar 1.02 (4) to the use of "institutional pharmacy" outside of subch. V?

d. Should the reference to "pharmacy" in s. Phar 7.54 (2) be changed to "institutional pharmacy" for clarity?

e. The definition for "general supervision" under s. Phar 7.60 (2) needs revision in order to be read as a complete sentence.